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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STEPHEN C. PORTER

Appeal 2008-003177
Application 09/933,316
Technology Center 1600

Decided: September 9, 2009

Before TONI R. SCHEINER, DONALD E. ADAMS, and ERIC GRIMES,
Administrative Patent Judges.

SCHEINER, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1, 3, 4, 9-11, 15-28, and 38-41, directed to an embolic composition useful in treating vascular abnormalities, including brain aneurysms. We have jurisdiction under 35 U.S.C. § 6(b).

BACKGROUND

“Vascular embolization often is the chosen method for controlling bleeding in the blood vessels or occluding blood supply to solid mass tumors or vascular aneurysms” (Spec. 1: 19-21).

“The present invention relates . . . [to] liquid polymer compositions capable of forming a solid embolic block upon administration in an ionic environment, such as blood” (*id.* at 1: 6-10).

STATEMENT OF THE CASE

Claim 1, the only independent claim on appeal, is representative of the subject matter on appeal:

1. A medical composition comprising:
 - a matrix-forming component comprising alkyl cyanoacrylate monomers, a stabilizer and a plasticizer;
 - a solid aggregate material comprising a radiopacifier; and
 - a polymeric non-cyanoacrylate rheology modifying agent that has an average molecular weight greater than 200,000, wherein the non-cyanoacrylate rheology modifying agent is a polymeric compound selected from the group consisting of poly(acrylates), poly(alkenes), poly(alkyl oxides), poly(amides), poly(carbonates), cellulosic polymers and copolymers, poly(dienes), poly(esters), poly(methacrylates), poly(saccharides), poly(siloxanes), poly(styrenes), poly(urethanes), poly(vinyl ethers), iodinated polymers and copolymers thereof, and mixtures thereof.

The Examiner relies on the following evidence:

Hechenberger	US 4,997,861	Mar. 5, 1991
Ricci	US 6,203,779 B1	Mar. 20, 2001
Krall	WO 00/44287	Aug. 3, 2000

Claims 1, 3, 4, 9-11, 15-28, and 39-41 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Krall and Ricci; while claims 1, 3, 4, 9-11, 15-28, and 38-41 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Krall, Ricci, and Hechenberger.

We reverse.

ISSUE

The issue raised by both rejections is the same: Has Appellant shown that the Examiner erred in concluding that a composition comprising alkyl cyanoacrylate monomers and a non-cyanoacrylate polymer with an average molecular weight greater than 200,000 would have been obvious over the disclosures of Krall and Ricci?

FINDINGS OF FACT

The Invention

FF1 Claim 1 is directed to a composition comprising:

- a matrix-forming component comprising alkyl cyanoacrylate monomers, a stabilizer, and a plasticizer;
- a solid aggregate material comprising a radiopacifier; and
- a polymeric non-cyanoacrylate rheology modifying agent that has an average molecular weight greater than 200,000.

FF2 The Specification teaches that “[a]ll the materials used are either incorporated into a single injectable embolic composition along with the matrix-forming components or can be included in one of a number of separately packaged mixtures that are combined prior to use” (Spec. 5: 24-29).

FF3 The embolic composition is liquid when initially combined, and “is delivered by any suitable device for administering a liquid composition” (Spec. 8: 6-7). “Upon contact with an ionic environment [e.g, blood], the liquid composition rapidly increases in viscosity, forming a solidified composition having the consistency of a rubbery polymeric matrix” (*id.* at 4: 21-24; 9: 15).

FF4 “[T]he term ‘stabilizer’ . . . means a compound or composition that can stop or slow down the rate of polymerization. Examples . . . are phosphoric acid and hydroquinone” (Spec. 12: 3-7).

FF5 Suitable plasticizers include aromatic esters and iodinated oils (Spec. 19: 6-10).

FF6 The radiopacifier, e.g., powdered gold, “is a compound or composition that selectively absorbs or deflects radiation making the material visible under x-ray, or any like imaging technique” (Spec. 11: 15-18, 28).

FF7 “The rheology modifying agent is capable of increasing the Newtonian viscosity of the composition and/or capable of imparting non-Newtonian behavior upon the liquid composition, such that it demonstrates thixotropic, pseudo-plastic, or plastic fluid behavior” (Spec. 6: 9-13).

Krall

FF8 Krall teaches that “[a]llyl alpha cyanoacrylates are a homologous series of organic molecules which polymerize and can adhere to moist living tissues” (Krall 2: 3-5), but certain derivatives polymerize too quickly or too slowly to be used in a controlled manner, are too adhesive, or are not cohesive enough (*id.* at 2-3).

FF9 Krall teaches that an embolic composition with an ideal “combination of properties in cohesion, stability, . . . [and] low catheter adhesion” (Krall 4: 7-9) can be achieved by combining:

- a monomer component comprising alkyl cyanoacrylate monomers and a polymerization inhibitor (e.g., phosphoric acid or hydroquinone);
- a second component comprising a polymer formed from an alkyl esterified fatty acid; a radiopacifier (e.g., powdered gold), and alkyl cyanoacrylate monomers.

(*id.* at 5: 7-11; 6: 8-12; 18: 4-16; 26: 27-31; 27: 17).

FF10 The first and second components are combined just prior to injection, and the initially liquid composition “polymerize[s] when it comes in contact with an anionic environment, or when it is deployed *in situ* in an existing space, e.g., the lumen of a blood vessel, or the sac of an aneurysm,” etc. (*id.* at 4: 25-30; *see also* 32: 26-32).

FF11 Krall teaches that an embolic composition “that polymerizes too quickly would hinder penetration, conversely a composition that polymerizes too slowly would make it difficult to precisely place the polymerized composition” (Krall 13: 21-25).

FF12 According to Krall, his two-component composition “remain[s] in a controllable state for a period of time in excess of 1 second after being deployed . . . [which] allows the practitioner to incrementally maneuver the deployment of the composition to its most ideal location” (Krall 12: 32 to 13: 5).

FF13 In addition, Krall’s composition “has low viscosity, which is essential for its administration by syringes and micro-catheters or other like devices” (Krall 32: 32 to 33: 2).

Ricci

FF14 Ricci discloses compositions for repairing abdominal aortic aneurysms. The composition is administered in liquid form, but “in situ, forms a coherent solid mass which adheres to vascular and/or prosthetic wall[s]” (Ricci, col. 3, ll. 38-39).

FF15 One embodiment of Ricci’s composition comprises a contrast agent suspended in a liquid cyanoacrylate prepolymer, e.g. cyanoacrylate monomers or reactive oligomers (Ricci, col. 6, ll. 62-65; col. 8, ll. 38-39).

FF16 Another embodiment of Ricci’s composition comprises a non-cyanoacrylate polymer, e.g., cellulose diacetate, a solvent, and a water insoluble contrast agent (Ricci, col. 3, ll. 41-45). The average molecular weight of the cellulose diacetate polymer is “preferably from about 50,000 to 200,000 and more preferably from about 100,000 to about 180,000” (Ricci, col. 5, ll. 31-35).

FF17 Ricci teaches that “cellulose diacetate polymers having a lower molecular weight will impart a lower viscosity to the composition as compared to higher molecular weight polymers. Accordingly, adjustment of the viscosity of the composition can be readily achieved by mere adjustment of the molecular weight of the polymer composition” (Ricci, col. 5, ll. 37-42).

FF18 Ricci does not disclose any compositions comprising mixtures of prepolymers and polymers.

PRINCIPLES OF LAW

When determining whether a claim is obvious, an Examiner must make “a searching comparison of the claimed invention - including all its limitations - with the teachings of the prior art.” *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995).

Moreover, “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. . . . [I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

ANALYSIS

Krall and Ricci: Claims 1, 3, 4, 9-11, 15-28, and 39-41

The Examiner acknowledges that Krall “lacks a polymeric non-cyanoacrylate rheology modifying agent that has an average molecular weight greater than 200,000” (Ans. 4). However, the Examiner finds that “Ricci describes embolic compositions comprising . . . [polymeric] non-cyanoacrylate rheology modifying agents” (*id.* at 4), including cellulose acetate polymers, where “[t]he cellulosic polymers . . . have an average molecular weight of about 200,000” (*id.* at 5). In addition, the Examiner notes that Ricci teaches that adjusting the molecular weight of the polymer affects the viscosity of the composition, and reasons that all of Ricci’s polymers are functional equivalents “for purposes of adjusting the viscosity of an embolic composition[]” (*id.*).

The Examiner's rationale is that it would have been obvious for one skilled in the art to add Ricci's non-cyanoacrylate polymers to Krall's embolic composition "and optimize the viscosity of such compositions for their own intended purpose by routine experimentation, because both polymeric units of Krall and Ricci are equally effective as embolic compositions" (Ans. 5).

Appellant contends that "there is nothing in the primary reference (Krall) about non-cyanoacrylate rheology modifying agents as claimed, let alone rheology modifying agents having molecular weights greater than 200,000" (Appeal. Br. 8).¹ In addition, Appellant contends that "Ricci does not teach the claimed elements of (1) non-cyanoacrylate rheology modifying agents having a molecular weight greater than 200,000[,] (2) a composition that includes a solid cyano[a]crylate and/or (3) a composition that combines a cyanoacrylate and a non-cyanoacrylate" (*id.* at 9).

Finally, Appellant contends that "Ricci draws a clear distinction between cyanoacrylate prepolymers and non-cyanoacrylate polymers . . . [and] unambiguously teaches that they are used separately" (App. Br. 10).

Appellant's arguments are persuasive. Krall is concerned with controlling the polymerization rate, cohesiveness and/or adhesiveness of embolic compositions (FF8, FF9, FF11, and FF12). We see nothing in Krall or Ricci to suggest that non-cyanoacrylate polymers are functionally equivalent to cyanoacrylate polymers for purposes of controlling the polymerization rate, cohesiveness, or adhesion of compositions containing cyanoacrylate monomers. While Ricci does teach that higher molecular

¹ All citations to the Appeal Brief are to the Revised Appeal Brief filed July 11, 2007.

weight cellulose diacetate polymers increase the viscosity of his polymer compositions, increasing viscosity is not an desired by Krall. On the contrary, Krall teaches that his embolic composition has a low viscosity, which is essential for its administration (FF13). Therefore, we don't agree with the Examiner that one of skill in the art would have had a reason to add a non-cyanoacrylate polymer to Krall's embolic compositions, much less one with a molecular weight greater than 200,000 (the upper limit of Ricci's polymers).

Krall, Ricci, and Hechenberger: Claims 1, 3, 4, 9-11, 15-28, and 38-41

Claim 38 depends indirectly from claim 1 and requires that the solid aggregate material further comprises an inorganic particulate material, e.g., fumed silica.

The Examiner relies on Hechenberger as disclosing "polymeric adhesive compositions containing cyanoacrylate and non-cyanoacrylate polymers in combination with fumed silica" (Ans. 6).

Hechenberger does not remedy the underlying deficiency in the Examiner's proposed combination of Krall and Ricci.

CONCLUSIONS OF LAW

Appellant has shown that the Examiner erred in concluding that a composition comprising alkyl cyanoacrylate monomers and a non-cyanoacrylate polymer with an average molecular weight greater than 200,000 would have been obvious over the disclosures of Krall and Ricci.

SUMMARY

The rejection of claims 1, 3, 4, 9-11, 15-28, and 39-41 under 35 U.S.C. § 103(a) as unpatentable over Krall and Ricci is reversed.

The rejection of claims 1, 3, 4, 9-11, 15-28, and 38-41 under 35 U.S.C. § 103(a) as unpatentable over Krall, Ricci, and Hechenberger is reversed.

REVERSED

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